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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,603	06/11/2001	Peter A. Ward	UM-06340	4222

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	17

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/878,603	Applicant(s) WARD ET AL.	
	Examin r F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 12-19* is/are pending in the application.

4a) Of the above claim(s) *16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a continuation of U.S. Application Serial Number 09/387,671.

Claims 3-11 have been canceled previously.

Claims 12-19 have been added.

Claims 1, 2 and 12-19 are currently pending.

Election/Restrictions

1. Amended claims 1-2 and newly submitted claims 12-15 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: in response to the Restriction Requirement mailed September 10, 2002, Applicant elected the invention of Group I, claims 1 & 2, drawn to "a composition comprising a peptide defined by SEQ ID NO: 14 or 15 and portions thereof," **without traverse** in the paper filed November 15, 2002. Amended claims 1-2 and newly submitted claims 12-15 comprise embodiments that are not encompassed within the scope of the elected invention. Claims drawn to 'portions' of at least 5 amino acid residues of SEQ ID NOs: 4, 5 and 16 read upon peptide sequences which are not 'portions' of the elected SEQ ID NOs: 14 and 15.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **claims 1, 2 and 12-15 are only being examined to the extent that they read upon SEQ ID NO: 14 and 15 and portions thereof**. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Newly submitted claims 16-19 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 16-19 are drawn to compositions comprising variant C-terminal truncated C5a peptide sequences which are not encompassed by the elected C5a peptide sequences SEQ ID NOs: 14 and 15 or portions thereof.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, **claims 16-19 are withdrawn from consideration** as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly, **claims 1, 2 and 12-15 are the subject of examination** in the present Office Action.

Claim Rejections - 35 USC § 112

3. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1, as amended, recites "wherein said portion is at least 5 amino acids in length" in line 4 of the claim. Page 5 of the specification, lines 1-8 for example, discloses,

> "the C-terminal truncated C5a peptide is between approximately 5 and 50 amino acids in length. In some embodiments, the C-terminal truncated peptide is approximately fifty amino acids in length. In other embodiments, the C-terminal truncated peptide is approximately five amino acids in length. In preferred embodiments, the C-terminal truncated peptides are 20 amino acids in length. In certain embodiments, the C-terminal truncated peptides are selected from SEQ ID NOS: 2, 4, 5, 14, 15 and 16."

The specification does not disclose or support an open-ended range of "at least 5," nor are ranges of 5-6 (corresponding to SEQ ID NO: 15), 5-9 (SEQ ID NOs: 14, 16) or 5-20 (SEQ ID NOs: 4, 5) supported. It is suggested that Applicant amend claim 1 to recite --approximately 5 amino acids in length--, which would read upon the shorter sequences. However, an open-ended recitation of "at least 5" is not supported by the specification or claims as originally filed and constitutes new matter.

Dependent claim 2 is included in this ground of rejection.

Applicant is reminded of the requirement to specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

4. Claims 12, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 12 is drawn to compositions comprising a C-terminal truncated C5a peptide of 5 to 50 amino acids in length. The claim reads upon C5a derived from any species. The breadth of the claim is

not supported by the written description in the disclosure as originally filed. The specification discloses that C5a peptides may be isolated from "various animals" (page 16, lines 20-28 for example). The genus recited is therefore very large and a great deal of sequence variation is encompassed by the instant claims. The specification discloses only human, rat bovine and porcine forms of C5a peptides. Thus the specification provides at most four members of the instant extensive genus. However, in University of California v. Eli Lilly and Co., 39 USPQ2d 1225 (Fed. Cir. 1995); the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The Court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. Therefore, the specification does not provide sufficient written support for the genus of polypeptides that includes any ortholog of a C5a peptide, irrespective of the inclusion of functional limitations. A description of what a material does, rather than of what it is, usually does not suffice. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. Dependent claims 14 and 15 are included in this ground of rejection.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

5. Claims 1, 2 and 12-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the peptides of SEQ ID NOs: 14 and 15 or fragments of SEQ ID NOs: 14 and 15 which are approximately 5 amino acids in length or 5-50 amino acids in length and are suitable for reduction of C5a binding to neutrophils, does not reasonably provide enablement for any fragment of SEQ ID NOs: 14 or 15 comprising "at least" 5 amino acids and C-terminal truncated C5a peptides which are not suitable for reduction of C5a binding to neutrophils. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 1 recites "wherein said portion is at least 5 amino acids in length" in line 4 of the claim. Page 5 of the specification, lines 1-8 for example, discloses,

> "the C-terminal truncated C5a peptide is between approximately 5 and 50 amino acids in length. In some embodiments, the C-terminal truncated peptide is approximately fifty amino acids in length. In other embodiments, the C-terminal truncated peptide is approximately five amino acids in length. In preferred embodiments, the C-terminal truncated peptides are 20 amino acids in length. In certain embodiments, the C-terminal truncated peptides are selected from SEQ ID NOS: 2, 4, 5, 14, 15 and 16."

The specification does not disclose or support an open-ended range of "at least 5." While it is acknowledged that the peptides of SEQ ID NOs: 14 and 15 are shorter than 50 amino acids in length, the specification does not teach how to make C-terminal truncated C5a peptides which comprise the open ended limitation of "at least 5 amino acids in length," only peptides of "approximately 5," "approximately 50," "between approximately 5 and 50," "of 20" or as defined by specific sequence identification number. Further, other than the ability to reduce C5a binding to neutrophils, the specification does not disclose any criteria for selecting peptides of the invention. Given the limited number of working examples in the present disclosure, the artisan would not be able to predict the full scope of peptides encompassed by the claims beyond those which fall within the disclosed lengths and those which reduce C5a binding to neutrophils.

Conclusion

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D. RV
Patent Examiner
September 8, 2003

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
9/8/03